Docket No. ENT/4



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Anita H. Lewin et al.

Application No.: 10/646,284 Confirmation No.: 9373

Filed : August 21, 2003

For : METHODS FOR PRODUCING HYDROXYALKYL

TROPANE ESTERS

Group Art Unit : 1625

Examiner : Not yet assigned

New York, New York

June 3, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith are an Information
Disclosure Statement, Form PTO-1449, and copies of
references cited therein in the above-identified
application. This Statement is submitted:

- [] within three months of the application filing date;
- [X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

Denise L. Loring (Reg. No. 32,259)

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Attorneys for Applicants

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I hereby certify that this Correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope Addressed to:

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P.O. Box 1450

Alexandria, VA 22313-1450 on

Claire J. Sairtif Van Goodman

Signature of Person Signing

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Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their representatives, make of record the following documents.*

United States Patents

Inventor	Patent No.	Issue Date
Somers et al.	5,663,345	September 2, 1997
Somers et al.	5,559,123	September 24, 1996

^{*} A complete Form PTO-1449 listing these documents is attached hereto.

Somers et al.	5,376,667	December 27, 1994
Somers	4,556,663	December 3, 1985
Somers	4,512,996	April 23, 1985
Somers	4,469,700	September 4, 1984
Rudner et al.	2,948,730	August 9, 1960
Rudner et al.	2,893,996	July 7, 1959

OTHER DOCUMENTS

- W.H. Anderson and D.T. Stafford, "Applications of Capillary Gas Chromatography in Routine Toxicological Analyses", <u>J. High Resolut. Chromatogr., Chromatogr. Commun.</u>, 6, pp. 247-254 (1983)
- M.R. Bell and S. Archer, "L(+)-2-Tropinone", <u>J. Amer.</u> Chem. Soc., 82, pp. 4642-4644 (1960)
- R. Bingham, "Esterene in the Treatment of Rheumatoid Arthritis", Arthritis News Today, 2(7), pp. 1-4 (1980)
- C.S. Boyer and D.R. Petersen, "Enzymatic Basis for the Transesterification of Cocaine in the Presence of Ethanol: Evidence for the Participation of Microsomal Carboxylesterases", J. Pharmacol. Exp. Ther., 260(3), pp. 939-946 (1992)
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- R.D. Budd, "Cocaine Radioimmunoassay Structure Versus Reactivity", Clin. Toxicol., 18(7), pp. 773-782 (1981)
- H. Bundgaard, <u>Design of Prodrugs</u>, Elsevier, Amsterdam, pp. 1-2 (1985)
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- T. Cohen et al., "The Direction of Opening of Styrene Oxide by Acetic Acid", J. Org. Chem., 27, p. 814-819 (1962)
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- F. Fish and W.D.C. Wilson, "Excretion of Cocaine and its Metabolites in Man", <u>J. Pharm. Pharmac.</u>, 21 Suppl., pp. 135S-138S (1969)
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- J.M.G. Galvez and A.P. de Abram, "Cocaina: Avances en su Investigacion", Bol. Soc. Quim. Peru, 56, pp. 12-20 (1989)
- W.L. Hearn et al., "Cocaethylene is More Potent than Cocaine in Mediating Lethality", Pharmacol.Biochem.Behav., 39(2), pp. 531-533 (1991)
- W.L. Hearn et al., "Cocaethylene: A Unique Cocaine Metabolite Displays High Affinity for the Dopamine Transporter", J. Neurochem., 56(2), pp. 698-701 (1991)
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- S.J. Mule et al., "Intracellular Disposition of [3H] Cocaine, [3H] Norcocaine, [3H] Benzoylecgonine and [3H] -

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Some of the documents listed above were cited in an International Search Report issued in connection with PCT application PCT/US03/26433 from which the present application claims priority. For the convenience of the Examiner, a copy of the Search Report is attached.

Applicants respectfully request that these documents be (1) considered by the Examiner prior to issuance of any

patent from this application; and (2) printed on any patent that may issue from this application. Applicants also request that a copy of enclosed Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

This Statement is submitted more than three months from the application filing date but before the mailing date of the first Office Action on the merits. In accordance with 37 C.F.R. § 1.97(b)(3), submission of this Statement requires no fee. However, if for any reason a fee is due, the Director is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this Statement is transmitted herewith.

Respectfully submitted,

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Claire J. Santil van Goodman

Signature of Person Signing

FORM PTO-1449

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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

ATTY. DOCKET NO.	APPLN. NO.
ENT/4	10/646,284
APPLICANT	CONFIRMATION NO.
Anita H. Lewin et al.	9373
FILING DATE	GROUP
August 21, 2003	1625

		U.S.	PATENT DOCUME	NTS			
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS		G DATE IF OPRIATE
	5,663,345	09/02/97	Somers et al.	546	127	Γ	
	5,559,123	09/24/96	Somers et al.	514	304		
	5,376,667	12/27/94	Somers et al.	514	304		
	4,556,663	12/03/85	Somers	514	304		
и	4,512,996	04/23/85	Somers	514	304		
	4,469,700	09/04/84	Somers	424	265	<u> </u>	
	2,948,730	08/09/60	Rudner et al.	260	292		
	2,893,996	07/07/59	Rudner et al.	260	292		
EXAMINER	DOCUMENT		GN PATENT DOCUI		CUDCI ACC	TRAN	SLATION
INITIAL	NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	YES	NO
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			applications of Capillary ogr., Chromatogr. Com			oxicologic	cal
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	R. Bingham, "Estere	ne in the Treatm	ent of Rheumatoid Arth	ritie" Arthritie N	lews Today 2(7) n	n 1_4 (10	180)

EXAMINER

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